

K251472 Inion CPS 1.5/2.0/2.5 Bioabsorbable Fixation SystemJul 11, 2025
59 days to decisionK251472 · Product code: **HBW** · Neurology
Source: <https://www.510kdatabase.net/k251472/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Plate, Cranioplasty (HBW)
Date received	May 13, 2025
Decision date	Jul 11, 2025
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Inion CPS 1.5 Baby Bioabsorbable Fixation System

APPLICANT

Company	Inion OY
Location	Tampere, FI
Contact	Hanne Kankaanpää
510(k) history	14 submissions · 13 cleared · 2005-2025

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